PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To:
SIM & MCBURNEY
6th Floor
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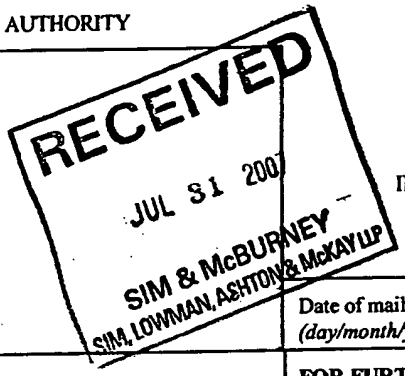


# PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43*bis*.1)

| | |
|---|---|
| | Date of mailing *(day/month/year)* 27 July 2007 (27-07-2007) |
| Applicant's or agent's file reference<br>9577-58 KAM | **FOR FURTHER ACTION**<br>See paragraph 2 below |

| International application No. | International filing date *(day/month/year)* | Priority date *(day/month/year)* |
|---|---|---|
| **PCT/CA2007/000548** | 03 April 2007 (03-04-2007) | 03 April 2006 (03-04-2006) |

International Patent Classification (IPC) or both national classification and IPC
IPC: ***A61K 9/54*** (2006.01), ***A61J 3/00*** (2006.01), ***A61K 9/24*** (2006.01)

Applicant
ODIDI, ISA ET AL

1. This opinion contains indications relating to the following items :

| | | |
|---|---|---|
| [X] | Box No. I | Basis of the opinion |
| [ ] | Box No. II | Priority |
| [X] | Box No. III | Non-establishment of opinion with regard to novelty, inventive step and industrial applicability |
| [X] | Box No. IV | Lack of unity of invention |
| [X] | Box No. V | Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement |
| [ ] | Box No. VI | Certain documents cited |
| [ ] | Box No. VII | Certain defects in the international application |
| [X] | Box No. VIII | Certain observations on the international application |

2. **FURTHER ACTION**
If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1*bis*(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

| Name and mailing address of the ISA/CA | Date of completion of this opinion | Authorized officer |
|---|---|---|
| Canadian Intellectual Property Office<br>Place du Portage I, C114 - 1st Floor, Box PCT<br>50 Victoria Street<br>Gatineau, Quebec K1A 0C9<br>Facsimile No.: 001-819-953-2476 | 11 July 2007 (11-07-2007) | Nasreddine Slougui 819-956-6132 |

**Box No. I** **Basis of this opinion**

1. With regard to the **language**, this opinion has been established on the basis of:

   [X] the international application in the language in which it was filed

   [ ] a translation of the international application into , which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b)).

2. [ ] This opinion has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43*bis*.1(a))

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of :

   a. type of material

      [ ] a sequence listing

      [ ] table(s) related to the sequence listing

   b. format of material

      [ ] on paper

      [ ] in electronic form

   c. time of filing/furnishing

      [ ] contained in the international application as filed.

      [ ] filed together with the international application in electronic form

      [ ] furnished subsequently to this Authority for the purposes of search.

4. [ ] In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

5. Additional comments :

**Box No. III** **Non-establishment of opinion with regard to novelty, inventive step and industrial applicability**

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of :

[ ] the entire international application

[X] claim Nos. 51 and 52

because:

[X] the said international application, or the said claim Nos. 51 and 52 relate to the following subject matter which does not require an international search *(specify)* :

Claims 51 and 52 are directed to a method for treatment of the human or animal body by surgery or therapy, are not required to be searched nor is a written opinion required by this Authority. Regardless, this Authority has established a written opinion based on the alleged effect or purpose/use of the product defined in claims 51 and 52.

[ ] the description, claims or drawings *(indicate particular elements below)* or said claim Nos. are so unclear that no meaningful opinion could be formed *(specify)* :

[ ] the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed *(specify):*

[ ] no international search report has been established for said claims Nos.

[ ] a meaningful opinion could not be formed without the sequence listing; the applicant did not, within the prescribed time limit:

[ ] furnish a sequence listing on paper complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Searching Authority in a form and manner acceptable to it.

[ ] furnish a sequence listing in electronic form complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Searching Authority in a form and manner acceptable to it.

[ ] pay the required late furnishing fee for the furnishing of a sequence listing in response to an invitation under Rule 13*ter*.1(a) or (b).

[ ] a meaningful opinion could not be formed without the tables related to the sequence listings; the applicant did not, within the prescribed time limit, furnish such tables in electronic form complying with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions, and such tables were not available to the International Searching Authority in a form and manner acceptable to it.

[ ] the tables related to the nucleotide and/or amino acid sequence listing, if in electronic form only, do not comply with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions.

[ ] See Supplemental Box for further details.

**Box No. IV** **Lack of unity of invention**

1. [ ] In response to the invitation (Form PCT/ISA/206) to pay additional fees the applicant has, within the applicable time limit :

   [ ] paid additional fees

   [ ] paid additional fees under protest and, where applicable, the protest fee

   [ ] paid additional fees under protest but the applicable protest fee was not paid

   [ ] not paid additional fees

2. [X] This Authority found that the requirement of unity of invention is not complied with and chose not to invite the applicant to pay additional fees.

3. This Authority considers that the requirement of unity of invention in accordance with Rules 13.1, 13.2 and 13.3 is

   [ ] complied with

   [X] not complied with for the following reasons :

   **Group A**: Claims 1-30, 51-56 (in part) and 57-66 are directed to a drug delivery composition comprising extruded spheroids, the spheroids comprising at least one active pharmaceutical ingredient; at least one extrusion-spheronization aid; at least one superdisintegrant; and at least one glidant, at least one lubricant; and/or at least one oil, a method of making the same as well as its use in pharmaceutical and medical fields .

   **Group B:** Claims 31-50 and 51-56 (in part) are directed to a drug delivery composition comprising coated spheroids having inert spheroids and at least one coating for the spheroids, the coating comprising at least one active pharmaceutical ingredient and at least one superdisintegrant and its use in pharmaceutical and medical fields.

4. Consequently, this opinion has been established in respect of the following parts of the international application :

   [X] all parts

   [ ] the parts relating to claim Nos.

**Box No. V** **Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1. Statement

| | | | |
|---|---|---|---|
| Novelty (N) | Claims | None | YES |
| | Claims | 1-66 | NO |
| Inventive step (IS) | Claims | None | YES |
| | Claims | 1-66 | NO |
| Industrial applicability (IA) | Claims | 1-66 | YES |
| | Claims | None | NO |

2. Citations and explanations :

**Cited documents:**

D1: US 6673367 (Euro-Celtique), 06 January 2004
D2: US 2003/0215507 (Wyeth), 20 November 2003
D3: US 6558704 (Gruenenthal GmbH), 06 May 2003
D4: US 2002/0002147 (R. Abramowitz et al), 03 January 2002
D5: US 5049394 (E. R. Squibb & Sons, Inc) 17 September 1991
D6: WO 2004/056354 (Ranbaxy Laboratories Limited), 8 July 2004
D7: WO 02/30398 (Euroceltique S.A.), 18 April 2002

**Novelty step:**

D1-D7 disclose a drug delivery composition comprising spheroids prepared by extrusion-spheronization, the spheroids comprising an active pharmaceutical drug, an extrusion spheronization agent such as microcrystalline agent cellulose and numerous excipients including a superdisintegarnt , a glidant, a lubricant or a oil. Also, the active pharmaceutical drug may be coated onto inert pharmaceutically acceptable beads or spheroids. All different ingredients comprised in the drug delivery composition are in different relative ratios including the ratios disclosed in the present application. This drug delivery composition is used for the controlled release of a desired amount of the drug time during a desired time in the gastro-intestinal tract. Therefore, claims 1-66 are not novel and do not comply with Article 33(2) of the PCT.

**Inventive Step:**

Claims 1-66 do not meet the criteria set for obviousness by Article 33(3) of the PCT as the claims lack novelty, they also lack an inventive step.

**Industrial Applicability:**

The subject matter of claims 1-66 is considered to be industrially applicable and thus complies with the requirements of Article 33(4) of the PCT.

**Box No. VIII Certain observations on the international application**

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made :

Item 1: Claims 1 and 31 do not comply with Article 6 of the PCT in that there is a broad statement at the point of alleged invention. The statement is so broad that it embraces all possible means without qualification for solving the problem facing the inventor, and is in effect no more than a re-statement of the problem or the desired result.

Item 2: Claims 1 and 32 do not comply with Article 5 of the PCT. The multiple use of the expression "at least" in these independent claims implies that the extent of protection may be expanded in some vague and imprecise way and renders the scope of the protection, sought by the applicant, indefinite and ambiguous.

Item 3: Reference to the name of "Aspirin" on page 17, "Cabosil", "Syloid", "Compritol", "Stear-O-Wet" and "Myvatex" on page 23, should be identified as trademarks according to Article 5 of the PCT.